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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/627,311	07/25/2003	Cydney C. Brooks	ADY-001B	1900

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EXAMINER	
MAYER, SUZANNE MARIE	

ART UNIT	PAPER NUMBER
1653	

DATE MAILED: 12/13/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/627,311	BROOKS, CYDNEY C.	
	Examiner	Art Unit	
	Suzanne M. Mayer, Ph.D.	1653	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *1* MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-71* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-71* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-31 and 34-35, drawn to a method for identifying an insulin response modulator, classified in class 435, subclass 7.1.

II. Claims 32 and 42, drawn to a modulator of insulin response and a pharmaceutical carrier, classified in class 514, subclass 1.

III. Claim 36, drawn to a method of modulating GLUT4 translocation in a subject, classified in class 435, subclass 7.1.

IV. Claim 37, drawn to a method of enhancing glucose clearance in an insulin resistant subject, classified in class 424, subclass 9.2.

V. Claim 38, drawn to a method of regulating blood glucose levels in a subject, classified in class 424, subclass 9.2.

VI. Claims 39 and 40, drawn to an antibody that binds IRAP and a pharmaceutical composition containing the same, classified in class 424, subclass 1.49.

VII. Claim 41, drawn to an antibody that binds TAP, classified in class 424, subclass 130.1.

VIII. Claim 43, drawn to a pharmaceutical composition containing an IRAP-interacting domain of TAP, classified in class 514, subclass 2.

IX. Claim 44, drawn to a method for identifying a compound used for diabetes treatment by using a cell that expressed TAP mRNA, classified in class 435, subclass 6.

X. Claims 45-47, drawn to a method for identifying a compound used for diabetes treatment by using a cell that expresses TAP protein, classified in class 435, subclass 7.1.

XI. Claims 48 and 49, drawn to a compound and pharmaceutical carrier that treats diabetes, classified in class 514, subclass 2.

XII. Claims 50-52, 61-65 and 66-67, drawn to a method of increasing TAP expression in a subject, classified in class 424, subclass 9.2.

XIII. Claims 53-56, drawn to a method of treating diabetes by administering a compound that increases TAP expression in a subject, classified in class 424, subclass 9.2.

XIV. Claims 57-59, drawn to a method of treating insulin resistance by administering TAP DNA or various viruses to a subject, classified in class 424, subclass 93.1.

XV. Claims 57, 58 and 60, drawn to a method of treating insulin resistance by administering to a subject TAP proteins, classified in class 435, subclass 7.1.

XVI. Claim 65, drawn to a pharmaceutical composition containing cells that overexpress TAP, classified in class 514, subclass 44.

XVII. Claims 68-71, drawn to a method of treating a subject with diabetes or insulin resistance, classified in class 435, subclass 6.

The inventions are distinct, each from the other because of the following reasons:

2. Inventions I, III-V, IX-X, XII-XV and XVII are patentably distinct methods and unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). The instant specification does not disclose that these methods would be used together. The method of identifying an insulin response modulator (group I), the method modulating GLUT4 translocation in a subject (group III), the method of enhancing glucose clearance in an insulin resistant subject (group IV), the method of regulating blood glucose levels in a subject (group V), the method of identifying a compound used for diabetes treatment by using a cell that expresses TAP mRNA (group IX), the method for identifying a compound used for diabetes treatment by using a cell that expresses TAP protein (group X), the method for increasing TAP expression in a subject (group XII), the method for treating diabetes in a subject through the administration of a compound that increases TAP expression (group XIII), the method of treating insulin resistance in a subject by administering TAP DNA or various virus' that carry TAP DNA (group XIV), the method of treating insulin resistance in a subject by administering TAP protein (group XV), the method of treating a subject with diabetes or insulin resistance by taking cells from said subject, treating the cells with a compound, and administering the treated cells to said subject (group XVII), are all unrelated as they comprise distinct steps and utilize different products which

demonstrates that each method has a different mode of operation. Each invention performs this function using structurally and functionally divergent material, ranging from testing methods that use different modes of operation such as *in vitro* assays (e.g. group 1), *in vivo* whole culture assays (e.g. group XII) to methods of treating subjects which can be performed by completely different modes of operations, materials and ultimately provide entirely different results. Furthermore, the majority of the methods have different status in the art as shown by their different classifications and searching the inventions of groups I, III-V, IX-X, XII-XV and XVII would impose a serious search burden since a separate search of each method would be required in order to determine patentability.

3. Inventions II, VI, VIII, XI and XVI are patentably distinct compositions and unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). The instant specification does not disclose that these compositions would be used together. The pharmaceutical composition of a compound that modulates insulin response (group II), the pharmaceutical composition of an antibody that binds IRAP (group VI), the pharmaceutical composition comprising an IRAP-interacting domain of TAP (group VIII), the pharmaceutical composition containing a compound that treats diabetes (group XI) and the pharmaceutical composition that contains cells that overexpress TAP (group XVI), are as all unrelated they comprise distinct compositions that utilize different products which demonstrates that each composition will have a different mode of

operation and effect. Each invention performs this function using structurally and functionally divergent products in the composition, ranging antibodies (group VI) to whole cells (group XVI) to protein domains (group VIII). Furthermore, these compositions have different status in the art as shown by their different classifications and searching the inventions of groups II, VI, VIII, XI and XVI would impose a serious search burden since a separate search of each composition would be required in order to determine patentability.

4. The antibody of group VII and the compounds, proteins and whole cells that make up the pharmaceutical compositions of groups II, VI, VIII, XI and XVI are unrelated. The pharmaceutical compositions are all unrelated to the antibody of group VII because they comprise distinct compositions that utilize different products which demonstrates that each composition will have a different mode of operation and effect. Furthermore, these compositions and the antibody of group VII have different status in the art as shown by their different classifications and searching each separate invention would impose a serious search burden.

Furthermore, the antibody of group VII is unrelated to the method steps of groups I, III-V, IX, X, XII-XV and XVII because the recited method steps do not require the antibody of group VII in carrying out or utilizing the claimed method steps. Furthermore, the separate inventions have acquired a separate status in the art as indicated by their different classifications which would subsequently induce an undue burden of examination upon the examiner.

5. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Suzanne M. Mayer, Ph.D. whose telephone number is 571-272-2924. The examiner can normally be reached on Monday to Friday, 8.30am to 5.00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jon Weber can be reached on 571-272-0925. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

SMM
29 November, 2004

ROBERT A. WAX
PRIMARY EXAMINER
AU 1653